

CLAIMS

1. Use of compound which is an imidazoquinoline amine,
imidazopyridine amine, 6,7-fused cycloalkylimidazopyridine amine, 1,2-bridged
5 imidazoquinoline amine, thiazolo- and oxazolo-quinolinamine or pyridinamine,
imidazonaphthyridine or tetrahydroimidazonaphthyridine amine in the manufacture
of a medicament to enhance an immune response to an antigen, wherein the
compound is administered topically or transdermally to the individual 12 to 36 hours
after a nucleic acid vaccine is administered, and wherein the nucleic acid vaccine
10 comprises a nucleotide sequence that encodes an HIV-1 gag protein or fragment
containing a gag epitope thereof and a second HIV antigen or a fragment encoding an
epitope of said second HIV antigen, operably linked to a heterologous promoter.

2. Use of a nucleotide sequence that encodes an HIV-1 gag protein or
15 fragment containing a gag epitope thereof and a second HIV antigen or a fragment
encoding an epitope of said second HIV antigen, operably linked to a heterologous
promoter in the manufacture of a nucleic acid vaccine, wherein 12 to 36 hours
subsequent to the administration of the nucleic acid vaccine to an individual a
compound which is an imidazoquinoline amine, imidazopyridine amine, 6,7-fused
20 cycloalkylimidazopyridine amine, 1,2-bridged imidazoquinoline amine, thiazolo- and
oxazolo-quinolinamine or pyridinamine, imidazonaphthyridine or
tetrahydroimidazonaphthyridine amine is administered topically or transdermally to
the individual.

25 3. Use according to claim 1 or 2 wherein the compound is an
imidazoquinoline.

4. Use according to claim 1 or 2 wherein the compound is imiquimod or
resiquimod.

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5. Use according to any one of the preceding claims wherein the nucleic acid

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vaccine is administered topically or transdermally.

6. Use according to any one of the preceding claims wherein the nucleic acid vaccine is administered in the form of particles.

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7. Use according to any one of the preceding claims wherein the compound is administered in the form of particles.

8. Use according to claim 6 or 7 wherein the nucleic acid vaccine or
10 compound is coated on a core carrier.

9. Use according to any one of claims 6 to 8 wherein the nucleic acid vaccine or compound is administered using a needleless syringe.

15 10. Use according to any one of the preceding claims in which the compound is administered in the form of a cream

11. Use according to any one of the preceding claims wherein the administration of the antigen or polynucleotide is repeated to provide a prime and
20 booster administration.

12. Use according to any one of the preceding claims wherein the second antigen is selected from the group consisting of: Nef, RT or a fragment containing an epitope of Nef or RT.

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13. Use according to any one of the preceding claims wherein the gag protein comprises p17.

14. Use according to claim 13 wherein the gag protein additionally
30 comprises p24.

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15. Use according to any one of the preceding claims wherein the gag sequence is codon optimised to resemble the codon usage in a highly expressed human gene.

5 16. Use according to any one claims 12 to 15 wherein the RT sequence or fragment thereof is codon optimised to resemble a highly expressed human gene.

17. Use according to any one of the preceding claims wherein the nucleotide sequence encodes a Nef protein or epitope thereof.

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18. Use according to any one of the preceding claims wherein the nucleotide sequence is selected from the group

- Gag (p17,p24) Nef truncate
- Gag (p17,p24) (codon optimised) Nef (truncate)
- 15 - Gag (p17,p24) RT Nef (truncate)
- Gag (p17,p24) codon optimised RT Nef (truncate)
- Gag (p17,p24) codon optimised RT codon optimised Nef truncate

19. Use according to any one of the preceding claims wherein the
20 heterologous promoter is the minimal promoter from HCMV IE gene.

20. Use according to claim 19 wherein the 5' of the promoter comprises exon
1.

25 21. Use according to any one of the preceding claims wherein the nucleic acid sequence is in the form of a double stranded DNA plasmid.

22. Use according to any one of the preceding claims wherein the nucleic acid sequence encodes Gag (or a fragment thereof which comprises an epitope) and
30 RT (or a fragment thereof which comprises an epitope) and Nef (or a fragment thereof which comprises an epitope) in any order.

23. Use according to claim 22 wherein wherein the nucleic acid encodes the proteins, or fragments thereof, in the sequence Nef-RT-Gag, RT-Nef-Gag or RT-Gag-Nef.

5 24. Use according to any one of the preceding claims wherein at least one of the proteins which is encoded by the nucleic acid is a fusion protein.

25. A product containing (i) a nucleic acid vaccine that comprises a nucleotide sequence that encodes an HIV-1 gag protein or fragment containing a gag epitope thereof and a second HIV antigen or a fragment encoding an epitope of said
10 second HIV antigen, operably linked to a heterologous promoter, and (ii) a compound which is an imidazoquinoline amine, imidazopyridine amine, 6,7-fused cycloalkylimidazopyridine amine, 1,2-bridged imidazoquinoline amine, thiazolo- and oxazolo-quinolinamine or pyridinamine, imidazonaphthyridine or
15 tetrahydroimidazonaphthyridine amine for sequential use, wherein the compound is administered topically or transdermally 12 to 36 hours after administration of the nucleic acid vaccine.

26. Method enhancing in an individual an immune response generated by a
20 nucleic acid vaccine, said method comprising administering a compound which is an imidazoquinoline amine, imidazopyridine amine, 6,7-fused cycloalkylimidazopyridine amine, 1,2-bridged imidazoquinoline amine, thiazolo- or oxazolo-quinolinamine or pyridinamines, imidazonaphthyridine or tetrahydroimidazonaphthyridine amine,
25 wherein the compound is administered topically or transdermally to the individual 12 to 36 hours after the nucleic acid vaccine is administered, and wherein the nucleic acid vaccine comprises a nucleotide sequence that encodes an HIV-1 gag protein or fragment containing a gag epitope thereof and a second HIV antigen or a fragment encoding an epitope of said second HIV antigen, operably linked to a heterologous
30 promoter.

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27. Method of preventing or treating HIV infection or AIDS comprising administering a nucleic acid vaccine that comprises a nucleotide sequence that encodes an HIV-1 gag protein or fragment containing a gag epitope thereof and a second HIV antigen or a fragment encoding an epitope of said second HIV antigen, operably linked to a heterologous promoter, and 12 to 36 hours subsequent to the administration of the nucleic acid vaccine administering a compound as defined in claim 26, wherein the compound is administered topically or transdermally.